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| 09/663,779 | 09/15/2000 | David R. Corbin | 38-21(51376)B | 2711 |
| 7590 03/05/2004 Timothy K Ball Phd Patent Department E2NA Monsanto Company 800 N Lindbergh Blvd St. Louis, MO 63167 | | | EXAMINER SMITH, CAROLYN L | |
| | | | ART UNIT 1631 | PAPER NUMBER |

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,779

Applicant(s)

CORBIN ET AL.

Examiner

Carolyn L Smith

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March and 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-35 and 38-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36, 37 and 51-53 is/are rejected.
- 7) ☒ Claim(s) 36-37 and 51-53 is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 15.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' amendments and remarks, including the amendments to claims 36-37 and the addition of claims 51-53, filed 3/13/03 and 12/15/03, are acknowledged. Applicants are correct in stating that claims 1-53 are pending and that claims 1-35 and 38-50 are withdrawn as being drawn to non-elected Groups.

Applicants' arguments, filed 3/13/03 and 12/15/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 36-37 and 51-53 are herein under examination.

Claim Objections

Claims 36-37 and 51-53 are objected to due to the inclusion of subject matter that has been non-elected due to a restriction requirement and therefore withdrawn from consideration. The non-elected subject matter in claims 36-37 and 51-53 is summarized as follows: These claims include SEQ ID Nos, besides SEQ ID NO: 1, which are non-elected sequence embodiments. Correction is suggested by deleting non-elected sequences.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36-37 and 51-53 are rejected under 35 U.S.C. 101 because the data, such as SEQ ID NO: 1, are considered nonfunctional descriptive material. As stated in the MPEP § 2106 (IV)(B)(1), "When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory."

Claims 36, 37, 51, and 53 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to lack any physical result performed outside of a computer.

As stated in MPEP § 2106, (IV)(B)(2)(b), to be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(B)(2)(b)(i)), or (B) be limited to a practical application within the technological arts (discussed in MPEP § 2106 (IV)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(B)(2)(b)(i), the independent physical acts may be post- or pre-computer processing activity as described below:

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer,

where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (In re Gelnovatch, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); *Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. *Schrader*, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval *Arrhythmia*, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; *Abele*, 684 F.2d at 909, 214 USPQ at 688; In re Taner, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(B)(2)(b)(ii), the computer-related process may be limited to a practical application in the technological arts as described below:

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 36, 37, 51, and 53 do not fulfill either of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

The specification does not provide support “*total* DNA”, “*first* computer readable medium”, or “*second* computer readable medium” as stated in lines 2, 6, 9, 11, and 13-20 of new claim 52. Written basis is provided for cDNA, genomic DNA, and synthetic DNA (page 9, line 2), but not for “total” DNA. Written basis is provided for a method of using computer media in isolating/identifying nucleic acids encoding insect inhibitory proteins or proteins involved in biosynthesis of antibiotics (specification, page 7, lines 16-18), but not the method steps using first and second computer readable medium as stated in claim 52. Because the introduction of “*total* DNA”, “*first* computer readable medium”, and “*second* computer readable medium” lacks written basis for new claim 52, as filed in Paper No. 17, filed on 3/13/03, it is considered NEW MATTER.

LACK OF ENABLEMENT

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable.

The rejection of claims 36 and 37 are maintained and presently applied to new claims 51-53 under 35 U.S.C. § 112, first paragraph.

Applicants state that it is unclear if the claims have been rejected as lacking sufficient enablement or if the claims are rejected because the specification lacks sufficient enablement. The claims are rejected as lacking enablement read in light of the specification. Claims 36-37 and 51-53 are directed to a composition comprising a computer readable medium including a sequence, such as SEQ ID NO: 1, which has a recited level of homology to preprotein translocase secA subunit (see Table 1) that Applicants' allege can identify sequences obtained from a *Bacillus* specie. A sequence stored on a computer readable medium cannot be predictably utilized for comparing identity and identifying a sequence from a *Bacillus* species, insect inhibitory protein, and/or antibiotic biosynthesis protein without first verifying that such a sequence (i.e. SEQ ID NO: 1) does indeed exhibit a conserved region or trait found in a *Bacillus*

species (as stated in claim 36, 37, and 53) or found in the alleged insect inhibitory protein and antibiotic biosynthesis protein, as stated in claims 51 and 52. The specification fails to provide such evidence necessary to support such allegations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36, 37, 51, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feitelson et al (P/N 6,242,669) in view of Fujiyama et al. (P/N 5,706,498) and *In re Gulack* (703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)).

Feitelson et al. describe a method for identifying genes from *Bacillus thuringiensis* that encode toxins active against insect pests, such as lepidopterans and coleopterans (abstract and col. 3, lines 1-7). Feitelson et al. describe genes and isolates that encode active toxins against pests which are identified using the methods and nucleotide sequences disclosed in their invention (col. 3, lines 56-62). Fietelson et al. describe isolating *Bacillus* and using DNA libraries (col. 15, lines 55-59). Fietelson et al. do not describe SEQ ID NO: 1 of the instant invention, a computer readable medium, or the steps of identifying, storing, and comparing sequences on a computer readable medium for sequence alignment.

Fujimiya et al. describe a computer readable medium (col. 8, lines 1-6) used in a computer-based system that contains a gene sequence database, a programming operation unit for determining the degree of similarity between target data with sequences from the database, and the retrieval of homologous sequences (abstract). Even though the computer readable medium described by Fujimiya et al. does not specify SEQ ID NO: 1 of the instant invention, the specific limitations of SEQ ID NO: 1 in this instant case does not distinguish the invention from the prior art in terms of patentability, because it is nonfunctional descriptive subject matter.

In re Gulack defines nonfunctional descriptive material to be descriptive material that is not functionally related to the substrate, in such a way that this descriptive material will not distinguish the invention from the prior art in terms of patentability. Also, the MPEP indicates that descriptive material unable to exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106, section VI). Due to the fact that the sequence in the instant case is merely stored for identity purposes by a computer without creating any functional

interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, this descriptive material alone does not impart functionality either to the data as structured, or to the computer.

Fietelson et al. state that *Bacillus thuringiensis* (*Bt*) genetic products can be highly toxic and exhibit high specificity to pests resulting in their endotoxin genes becoming commercially valuable (col. 1, lines 16-29). Fietelson et al. state that while extensive research has been performed in finding new *Bt* isolates, the discovery of new *Bt* isolates remains an empirical and unpredictable art (col. 2, lines 38-43). Fietelson et al. provide methods for identifying *Bt* genes (abstract), but state that various modifications of their invention can be made (col. 38, lines 1-6). As Fujimiya et al.'s invention contains a computer readable medium and gene database retrieval system, a skilled artisan would have been motivated to include any nucleic acid sequence, such as commercially valuable *Bt* genes as stated by Fietelson, or any other sequence already identified and analyzed into the database (abstract and *In re Gulack*). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include non-functional descriptive material, such as SEQ ID NO: 1, of the instant invention (*In re Gulack*) to Fujimiya et al.'s computer readable medium and database as the sequence had already been identified and analyzed, as stated by Fujimiya et al. (abstract) in order to effectively execute an operation of retrieval of other gene sequences as stated by Fujimiya et al. Thus, Fietelson et al. (P/N 6,242,669), in view of Fujiyama et al. (P/N 5,706,498) and *In re Gulack*, motivate the limitations in claims 36, 37, 51, and 53.

Conclusion

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 25, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER